Medical Device Alert

Action

Ref: MDA/2010/036 Issued: 06 May 2010 at 15:00

Device

All anaesthetic breathing systems, anaesthetic machines and anaesthetic ventilators.

Problem

The MHRA continues to receive reports of inadequate patient ventilation and oxygenation where harm could have been avoided if an alternative means of ventilation had been used earlier. These incidents occurred because of misconnection, entrapment or occlusion of the anaesthetic breathing systems, or because the anaesthetic machine or ventilator had failed.

In one particular incident an anaesthetic breathing system was wrongly connected to the auxiliary common gas outlet of an anaesthetic machine. The effects of this were wrongly interpreted as bronchospasm and the usual drug regimens were administered. The time taken to finally identify that this was a problem with the equipment meant that the patient was harmed.

Whilst such equipment issues are uncommon, they should be considered as a matter of course when problems with patient ventilation occur.

Action

- Prior to the induction of anaesthesia ensure that an alternative means of ventilation is immediately available e.g. self-inflating bag and an oxygen cylinder with suitable connections, as recommended by the Association of Anaesthetists of Great Britain and Ireland (AAGBI) in their guidelines 'Checking Anaesthetic Equipment 3 (2004)'. This publication is available from their website (www.aagbi.org).
- When problems with patient ventilation occur, consider the immediate use of a self-inflating bag. This may identify the site of the problem, while maintaining ventilation and oxygenation.
- Ensure the self-inflating bag is directly attached to the endotracheal tube/airway device, removing all parts of the existing circuit including the catheter mount.

The AAGBI and the Royal College of Anaesthetists endorse these actions.

CAS deadlines

Action underway: 27 May 2010
Action complete: 17 June 2010

Action by

Anaesthetic staff.

Distribution

This MDA has been distributed to:

- NHS trusts in England (Chief Executives)
- Care Quality Commission (CQC) (Headquarters)
- HSC trusts in Northern Ireland (Chief Executives)
- NHS boards in Scotland (Chief Executives)

Onward distribution

Please bring this notice to the attention of all who need to know or be aware of it. This may include distribution by:

Trusts to:

CAS and SABS (NI) liaison officers for onward distribution to all relevant staff including:

- Anaesthesia, directors of
- Anaesthetic nursing staff
- Anaesthetists
- Operating department practitioners
- Risk Managers
- Theatre managers

Care Quality Commission (CQC) (England only) to:

The MHRA considers this information to be important to:

- Hospitals in the independent sector
- Independent treatment centres

England

If you are in England, please send enquiries about this notice to the MHRA, quoting reference number **MDA/2010/036 or 2009/012/014/401/004.**

Technical aspects
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How to report adverse incidents

Please report via our website http://www.mhra.gov.uk

Further information about **CAS** can be found at https://www.cas.dh.gov.uk/Home.aspx

Northern Ireland

Alerts in Northern Ireland will continue to be distributed via the NI SABS system.

Enquiries and adverse incident reports in Northern Ireland should be addressed to:

Northern Ireland Adverse Incident Centre
Health Estates Investment Group
Room 17
Annex 6
Castle Buildings
Stormont Estate
Dundonald BT4 3SQ

Tel: 02890 523 704
Fax: 02890 523 900

Email: NIAIC@dhsspsni.gov.uk

http://www.dhsspsni.gov.uk/index/hea/niaic.htm

How to report adverse incidents in Northern Ireland

Please report directly to NIAIC, further information can be found on our website http://www.dhsspsni.gov.uk/niaic

Further information about **SABS** can be found at http://sabs.dhsspsni.gov.uk/

Scotland

Enquiries and adverse incident reports in Scotland should be addressed to:

Incident Reporting and Investigation Centre
Health Facilities Scotland
NHS National Services Scotland
Gyle Square
1 South Gyle Crescent
Edinburgh EH12 9EB

Tel: 0131 275 7575
Fax: 0131 314 0722

Email: nss.iric@nhs.net

http://www.hfs.scot.nhs.uk/online-services/incident-reporting-and-investigation-centre-iric/

Wales

Enquiries in Wales should be addressed to:

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